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Valaie

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(54) **HAEMOSTATIC VALVE DEVICE**

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CPC ***A61M 39/0693*** (2013.01); ***A61M 39/0606*** (2013.01); *A61M 2039/0633* (2013.01); *A61M 2039/0653* (2013.01)

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USPC 604/167.01, 167.02, 167.03, 167.04, 604/167.05, 167.06, 164.04, 164.05, 604/288.02, 103.03, 278, 256, 251, 237; 277/630, 637
See application file for complete search history.

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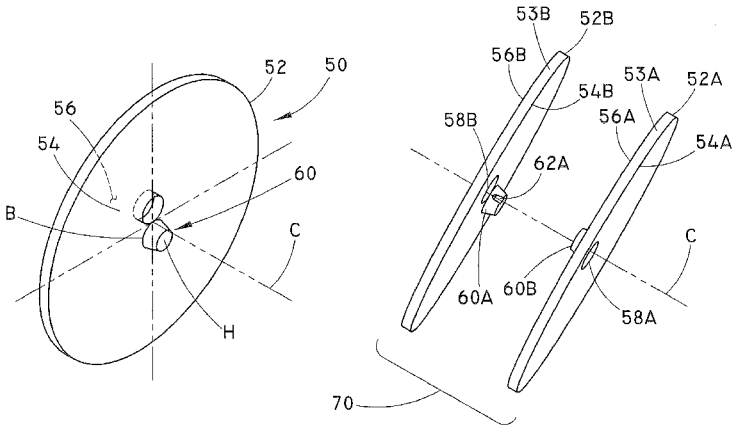
(57) **ABSTRACT**

A haemostatic valve device (**10**) comprises a disk valve (**52***a*) having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, and an opening (**58***a*) formed in the valve body for providing communication through the disk valve. In some examples, the disk valve comprises a nipple (**60***b*), axially offset from the opening, extending outwardly and away from at least one of the first and second surfaces. The haemostatic valve device may further comprise a second disk valve (**52***b*) and the nipple (**60***b*) may be removably disposed within, and sealingly engage, an opening (**58***b*) of the second disk valve.

9 Claims, 8 Drawing Sheets



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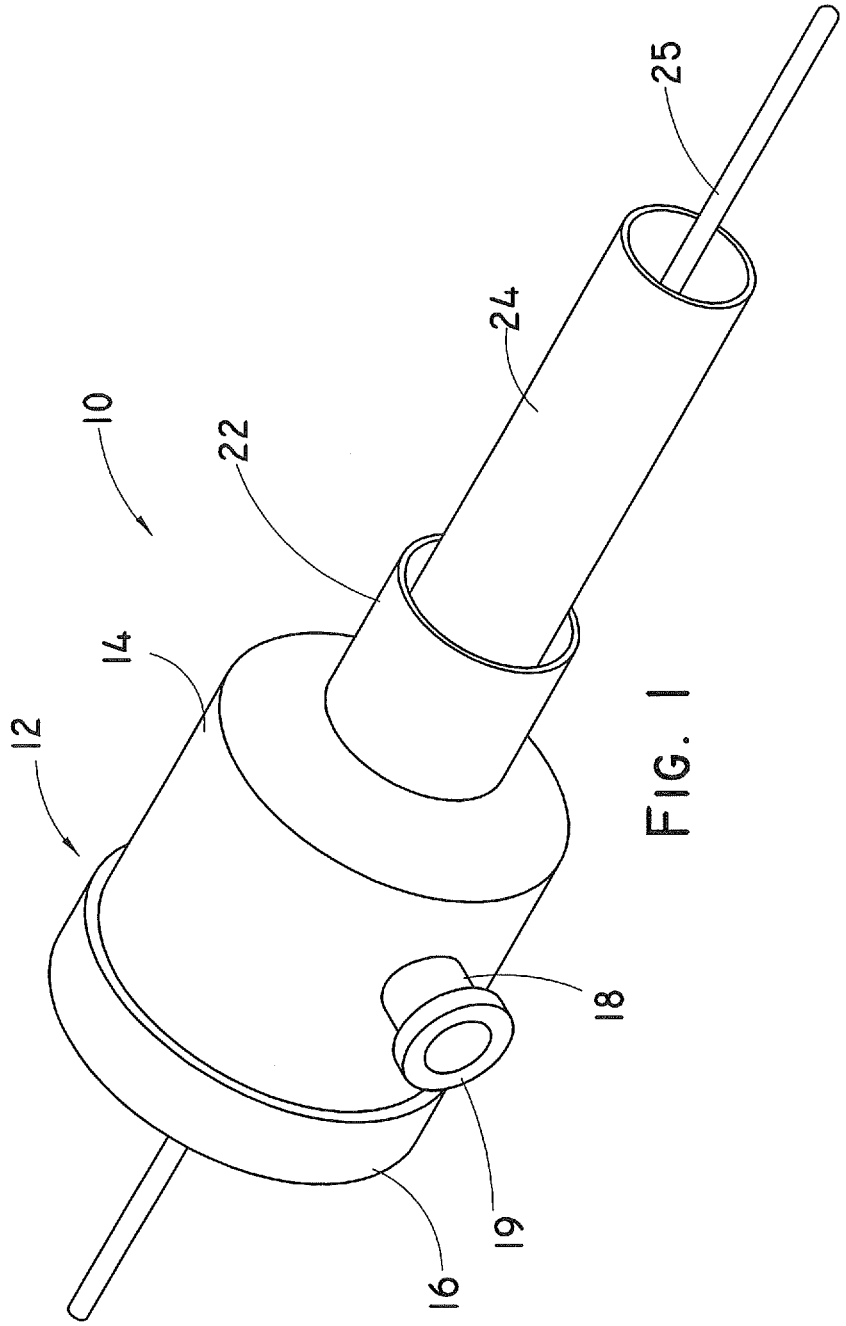

FIG. 1

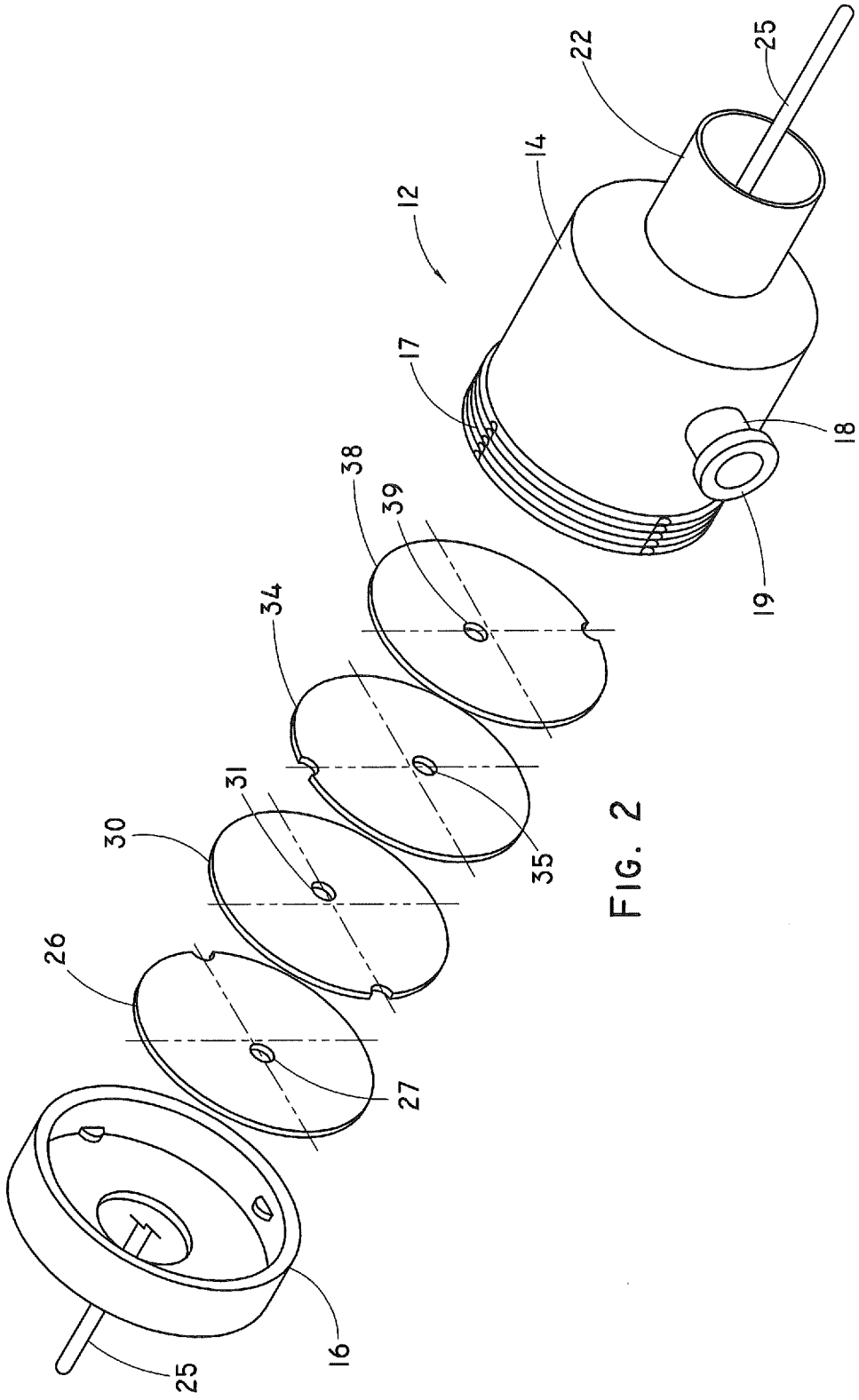

FIG. 2

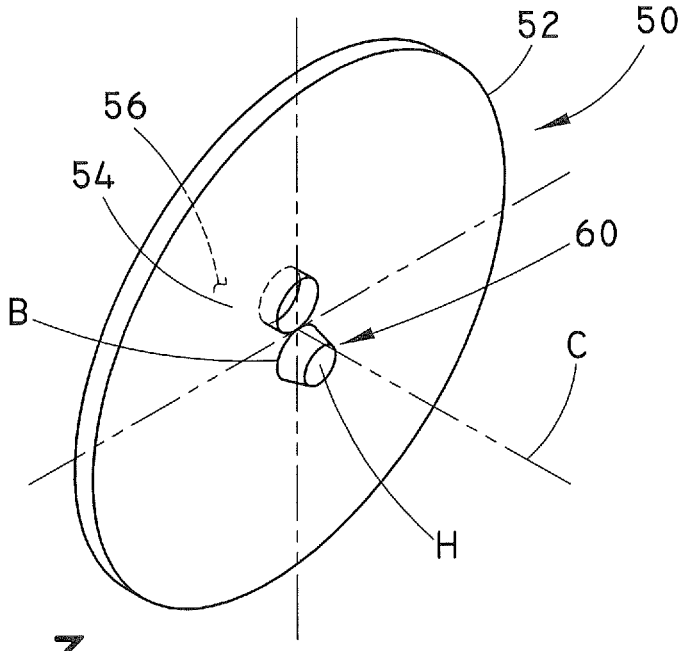
52
50
56
54
60
B
C
H

FIG. 3

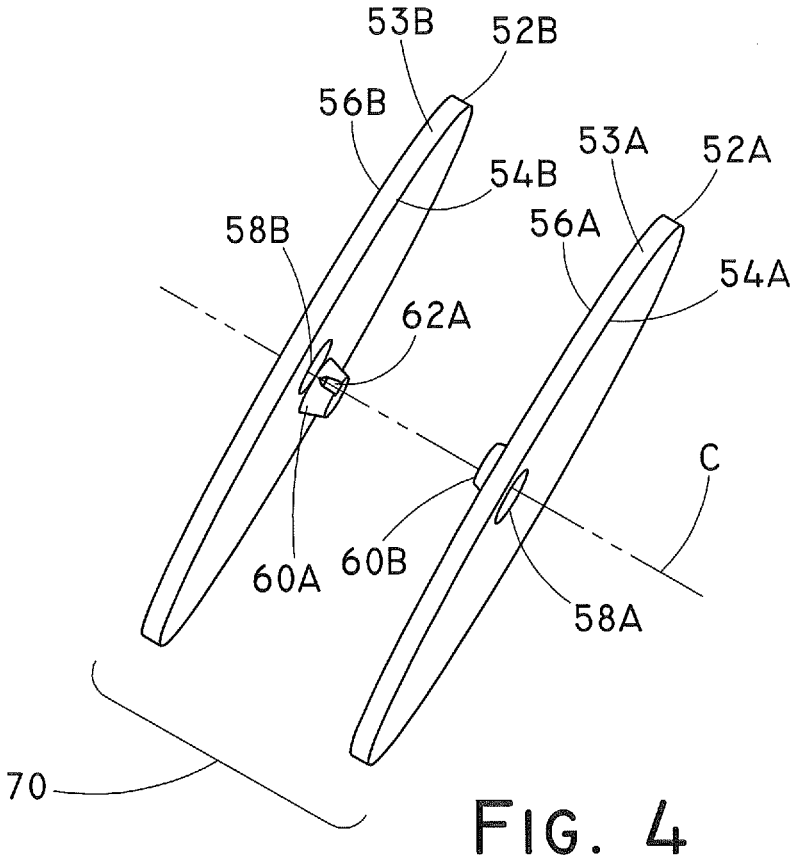
53B
52B
56B
54B
53A
52A
58B
56A
54A
62A
C
60A
60B
58A
70

FIG. 4

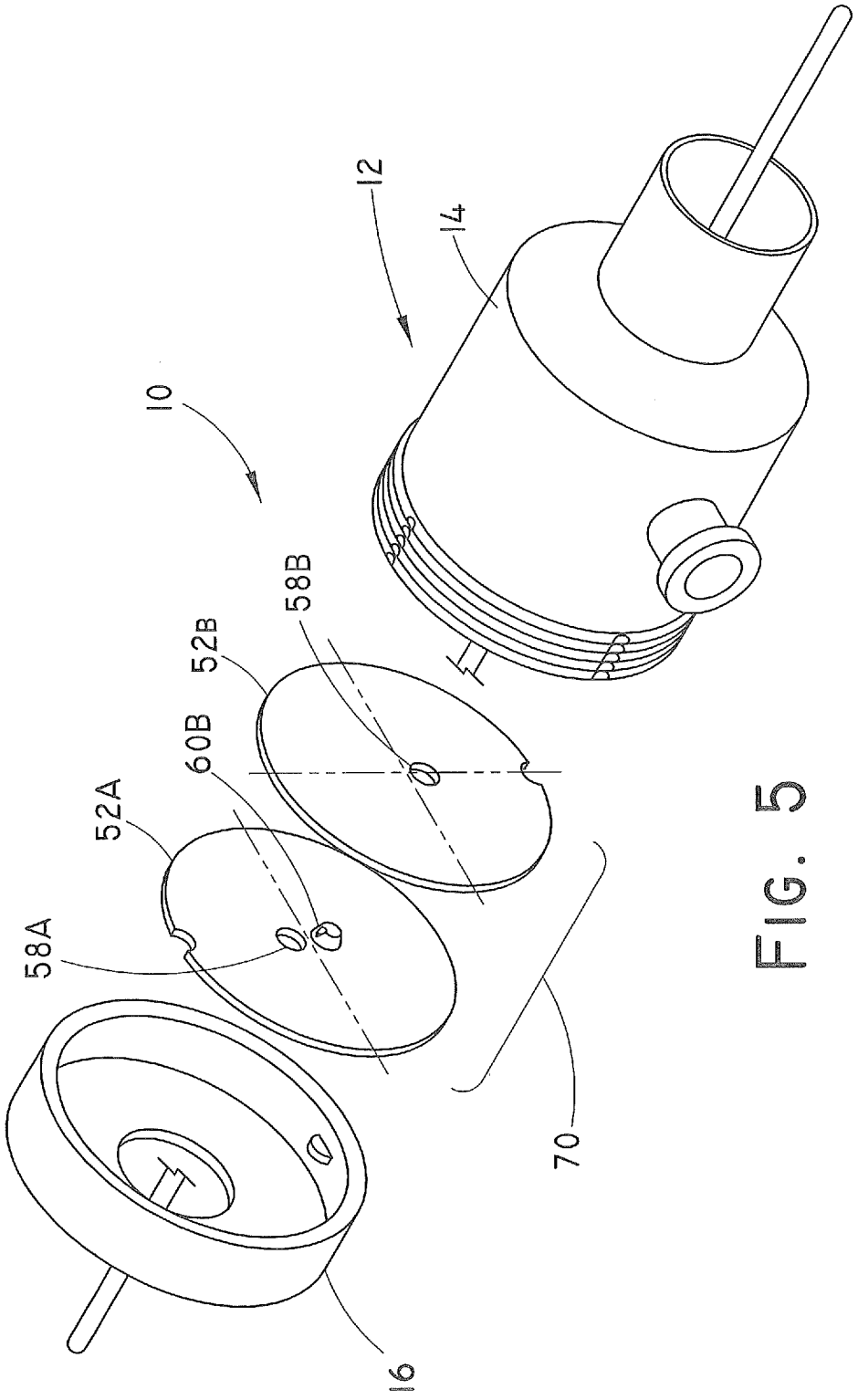

FIG. 5

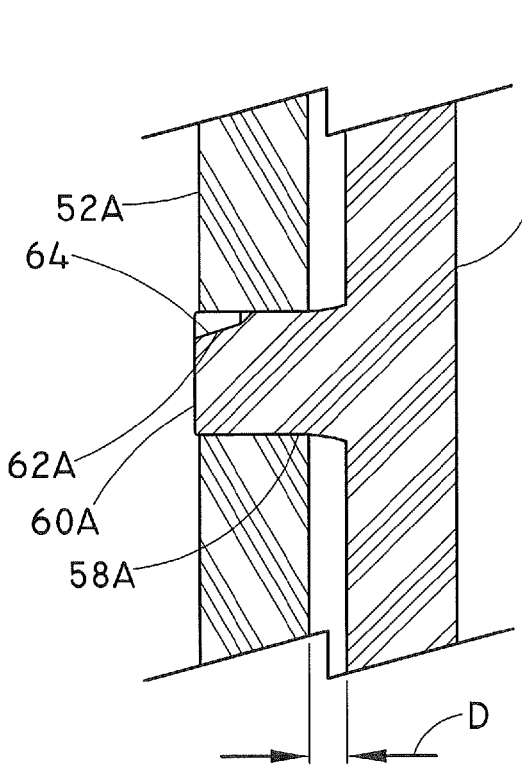

FIG. 6

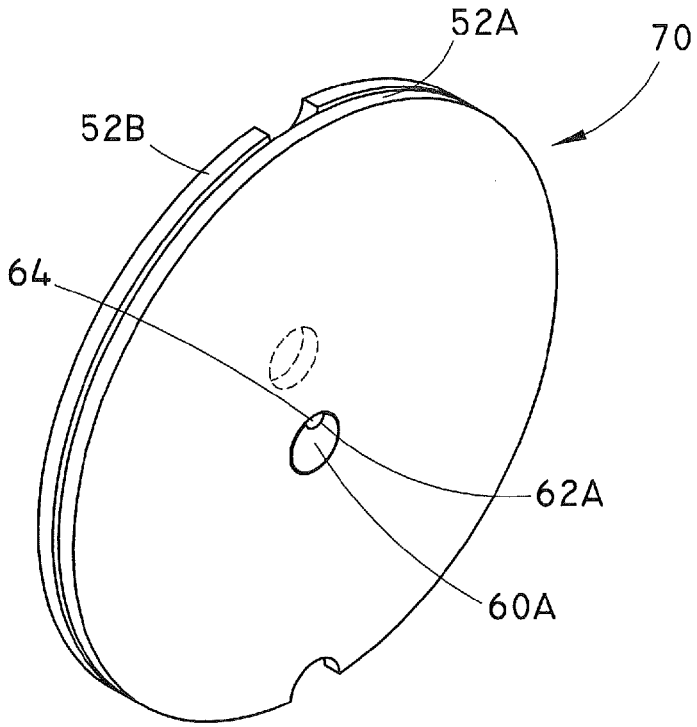

FIG. 8

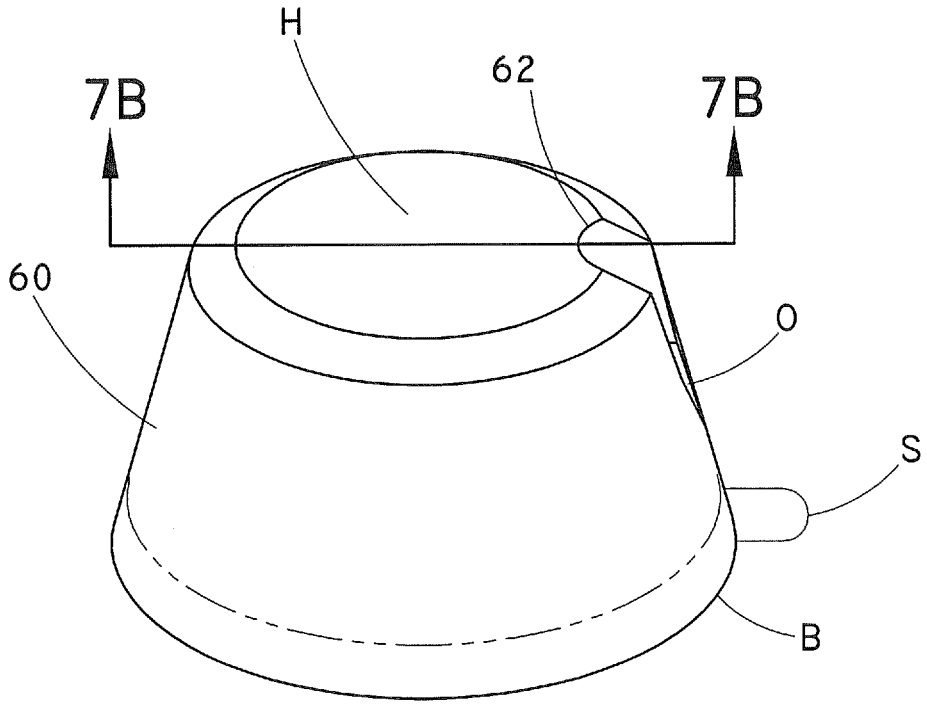

FIG. 7A

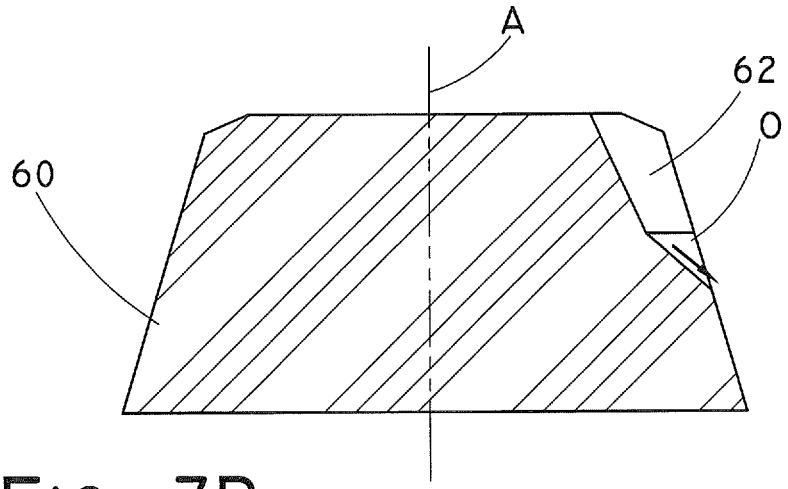

FIG. 7B

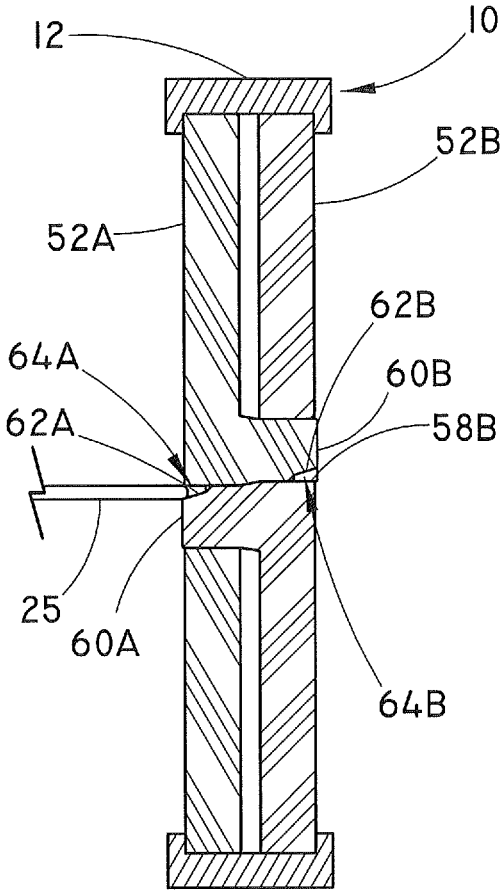
12
10
52B
52A
62B
64A
60B
62A
58B
25
60A
64B

FIG. 9A

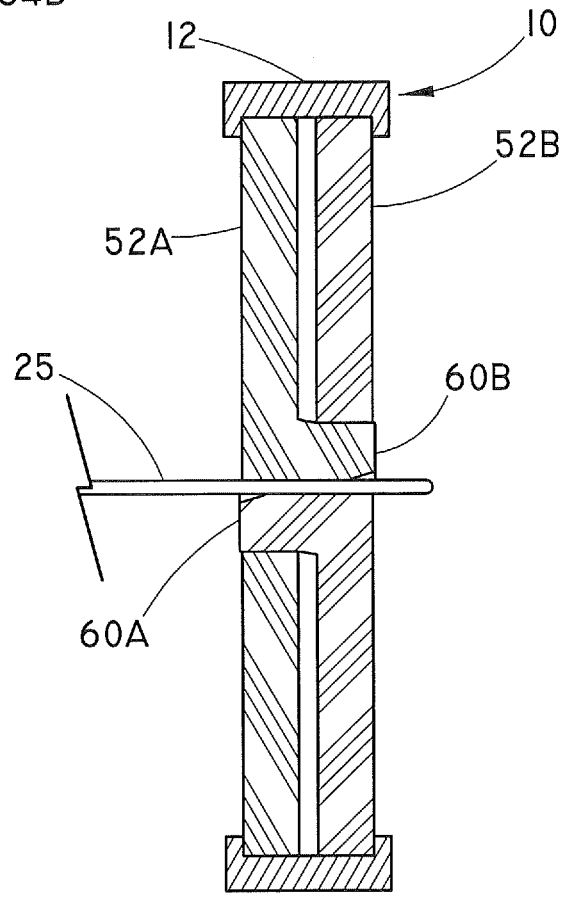
12
10
52B
52A
25
60B
60A

FIG. 9B

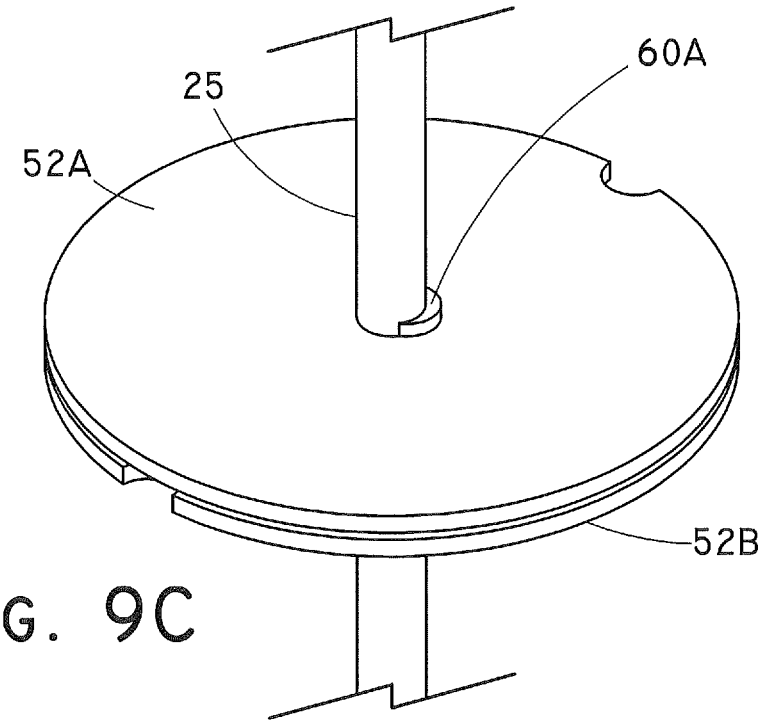

FIG. 9C

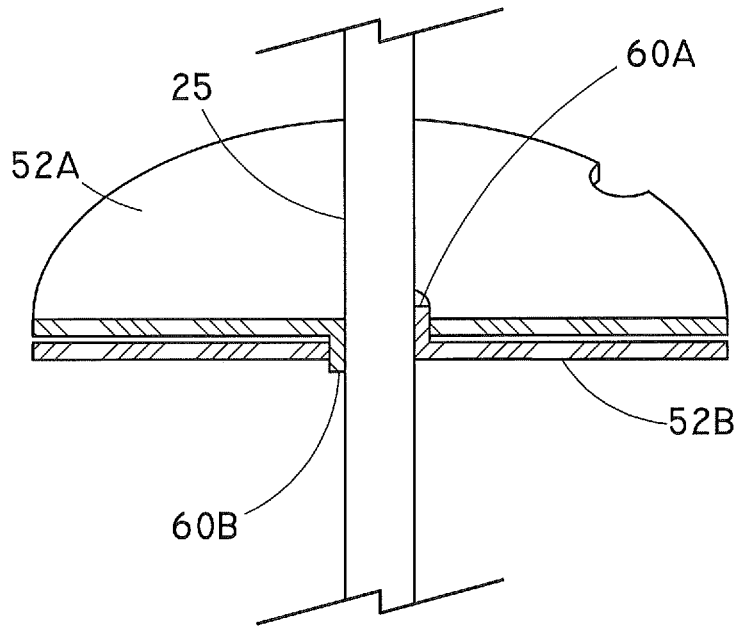

FIG. 9D

HAEMOSTATIC VALVE DEVICE

RELATED APPLICATIONS

The present patent document is a §371 filing based on PCT Application Serial No. PCT/US2010/040380, filed Jun. 29, 2010 (and published as WO 2011/008537 A1 on Jan. 20, 2011), designating the United States and published in English, which claims the benefit of the filing date under 35 U.S.C. §119(e) of Provisional U.S. Patent Application Ser. No. 61/221,343, filed Jun. 29, 2009. All of the foregoing applications are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates to haemostatic valves, devices, and systems, and methods of making and using same.

BACKGROUND OF THE INVENTION

Numerous procedures have been developed that involve the percutaneous insertion of a medical device into a vessel. Such a device may be introduced into the vessel by a variety of known techniques. For example, a wire guide may be introduced into a vessel using the Seldinger technique. This technique involves making a surgical opening in a vessel by a needle and inserting a wire guide into the vessel through a bore in the needle. The needle can be withdrawn, leaving the wire guide in place. An introducer device is then inserted over the wire guide and into the vessel. The introducer device may be used in conventional fashion to insert a variety of types of medical devices, such as catheters, cardiac leads, balloons, stents, stent grafts, and the like.

One of the challenges associated with endoluminal procedures is controlling the flow of bodily fluids within the introducer device during the procedure. Haemostatic devices and valve systems control the flow of blood through an introducer. US-A-2007/0078395 entitled "Haemostatic Valve System", the disclosure of which is incorporated herein by reference, discloses numerous examples of haemostatic valve devices and systems that use disk valves to control fluid flow. US-A-2007/0078395 discloses, among other things, disk valves with holes that are offset from the radial center of the disk. In some examples, a valve system includes several such disks, aligned so that the holes are not substantially overlapping. Additional valve disks may be added to improve the pressure rating of such a valve system.

Using a large number of disk valves to provide a desired seal can present challenges. For example, as the number of disk valves increases, the total force required to insert a medical device through the valve system may increase. In addition, even when the valves are in a "closed" configuration, the holes in the disk valves remain open and may provide a pathway for leakage through the haemostatic device.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved haemostatic valve, valve and medical introducer or deployment device incorporating such a valve.

According to an aspect of the present invention, there is provided a haemostatic valve device including a disk valve including a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, an opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces; wherein the nipple is axially offset from the opening.

According to another aspect of the present invention, there is provided a haemostatic valve device including a first disk valve having a valve body with an opening therein for providing communication through the first disk valve; and a second disk valve having a valve body with an opening therein for providing communication through the second disk valve, and a plug removably disposed within, and sealingly engaging, the opening of the first disk valve to limit fluid flow through the first disk valve.

Various examples of valve devices and systems are described throughout the specification and depicted in the drawings. In one example, a haemostatic valve device is provided and comprises a disk valve having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, an opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces of the valve body.

Such a disk valve may be used, for example, in combination with a second disk valve to provide a haemostatic valve device with superior haemostatic properties. In these examples, the valves are arranged so that the nipple is removably disposed within, and sealingly engages, an opening of the second disk valve. The nipple acts as a stopper or plug for the opening of the second disk valve, thereby limiting fluid flow through the opening. A medical device, such as a guide wire, may be inserted through the opening of the second disk valve to displace the nipple, break the sealing engagement, and allow the wire to pass through the openings. Such devices have a more robust sealing structure and may result in a better pressure rating than devices that use only traditional disk valves.

In some embodiments, the nipple has a tapered contour. The nipple may be attached to the valve body by any means. For example, the nipple and the valve body may comprise a monolithic structure. In examples comprising a second disk valve, the second disk valve may comprise a nipple that is removably disposed within, and sealingly engages, the opening of the first disk valve.

In another embodiment, a haemostatic valve device is provided and comprises a first disk valve and a second disk valve. Each disk valve has a valve body with an opening formed in the valve body for providing communication through the disk valve. The second disk valve may have a plug removably disposed within, and sealingly engaging, the opening of the first disk valve to limit fluid flow through the first disk valve. The first disk valve may, likewise, have a plug removably disposed within, and sealingly engaging, the opening of the second disk valve. In preferred examples, the opening of the first disk valve is axially offset from the opening of the second disk valve.

Guiding a device through first and second openings in such devices can be more challenging than in examples where the openings are axially aligned. Therefore, structures are disclosed herein for guiding a medical device between the first and second openings. For example, the plug of the second disk valve may have a dent with a contour that slopes towards the opening of the second disk valve. The plug of the second disk valve and the opening of the first disk valve may cooperate to form a niche having a contour that slopes towards the opening of the second disk valve. When a medical device, for example a guide wire, is inserted into the chamber, the dent

and/or niche acts as a locator for the sealed opening of the first disk valve, biases the manner in which the medical device passes through the opening, and causes the opening to stretch in a predetermined direction, thereby deflecting and guiding the medical device towards the opening of the second disk valve.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention are described below, by way of example only, with reference to the accompanying drawings, in which:

FIG. **1** is a perspective view of a haemostatic device;

FIG. **2** is an exploded view of the device shown in FIG. **1**;

FIG. **3** is a perspective view of an embodiment of valve device;

FIG. **4** is a perspective view of another embodiment valve device;

FIG. **5** is an exploded view of an embodiment of haemostatic device including a valve device similar to the one shown in FIG. **4**;

FIG. **6** is a cross-sectional view of the valve device shown in FIG. **4**;

FIG. **7**A is a perspective view of an embodiment of nipple for the valve devices disclosed herein;

FIG. **7**B is a cross-sectional view of the nipple of FIG. **7**A;

FIG. **8** is a perspective view of the valve device shown in FIG. **4**; and

FIGS. **9**A-**9**D depict various views of a valve device in stages of use.

TERMINOLOGY

Throughout the specification, when referring to a medical device, or a portion of a medical device, the terms "distal" and "distally" shall denote a position, direction, or orientation that is generally towards, or in the direction of, the patient when the device is in use. The terms "proximal" and "proximally" shall denote a position, direction, or orientation that is generally away from the patient, or closer to the operator, during use of the device.

The term "medical device" refers to any device, object, or structure, that supports, repairs, or replaces, is configured to support, repair, or replace, or that may be used, alone or in combination with other devices, objects, or structures, to support, repair, or replace a body part or a function of that body part. Examples of medical devices include, but are not limited to, sheaths, catheters, guide wires, cardiac leads, vessel occlusion devices, filters, stents, stent grafts, and delivery and deployment devices.

The term "opening" includes one or more apertures, perforations, gaps, spaces, holes, slits, slots, or the like.

The term "monolithic" refers to structures, or portions of structures, that are formed as a single integral piece, rather than being separately formed and attached.

The term "disk" describes structures with circular contours, as well as structures with contours that would not be described as circular (such as square, octagonal, and the like). Thus, the term "disk valve" describes valve structures that are circular, as well as structures that are not circular.

The term "niche" refers to a dent, detent, depression, cut, score, notch, line, recess, dimple, or other like structure in a surface.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **1** and **2** illustrate a perspective view and exploded view, respectively, of one embodiment of introducer device **10**. Various features of this device are described in detail in US-A-2007/0078395 where more specific details can be found. The device **10** includes a valve housing **12** having a main body **14** and an end cap **16**. Main body **14** and end cap **16** may be joined in any conventional fashion, such as by a screw fit or a snap fit. AS can be seen in FIG. **2**, main housing body **14** has one or more screw threads **17** that correspond with a lip or other suitable structure in the end cap. Housing **12** may also include a side-arm spout **18** extending in a generally transverse direction from main housing body **14**. Spout **18** may be used for transmitting or aspirating a fluid or drug in a conventional fashion, and preferably includes a lip **19** sized and shaped for threaded or like engagement with a tube or other device (not shown). The distal end of main housing body **14** comprises a smaller diameter portion **22**. A removable sheath **24** extends distally from smaller diameter portion **22** of housing **12** in conventional fashion. A wire guide **25** extends through device **10**.

The device comprises a plurality of disk valves **26**, **30**, **34**, **38**, as shown in FIG. **2**, disposed within a chamber of the housing **12**. The valves **26**, **30**, **34**, **38** are axially aligned between main body **14** and end cap **16**. Each valve has an opening **27**, **31**, **35**, **39** (depicted, in this example, as a generally circular hole) that allows communication through the valve of fluids, such as blood. The openings **27**, **31**, **35**, **39** are preferably sized to enable communication or passage of a medical device, such as a catheter. In this example, the openings are each axially offset from the radial center of the respective disk. To improve the pressure rating of the valve system, the valves are arranged so that openings in immediately adjacent disks are not substantially overlapping. The device shown in FIGS. **1** and **2** includes numerous other features that are described in US-A-2007/0078395.

The use of disks in haemostatic valve systems is well known. The disks preferably comprise a material with sufficient elasticity to enable an opening formed in the disk to stretch to the extent required to allow a medical device to pass through the disk, and to enable the disk and opening to substantially return to a pre-stretched condition when the medical device is removed. Examples of suitable materials include silicone and urethane, although any other suitable composition known in the art for such purposes may also be used.

FIG. **3** depicts an embodiment of disk valve **50** that may be used along with, or instead of, a conventional disk valve. The valve **50** includes a valve body **52** having a first surface **54** facing a first direction, a second surface **56** facing a second direction, opposite the first direction, and an opening **58** between the first and second surfaces. The valve body **52** preferably comprises an elastic material, as described above, and is fluid impermeable.

Opening **58** provides a path for communication through the valve **50**. Opening **58** is preferably sized and configured to allow passage of a medical device (not shown) through the valve **50**, as described above. In some examples, opening **58** may have a generally circular shape and have an unexpanded diameter of approximately 0.1 mm. Such an opening may expand to 50 or 60 times its diameter, depending on the elasticity of the disk material. In other embodiments, opening may have a non-circular shape and/or may have an unexpanded dimension that is less than, or greater than, 0.1 mm.

In the embodiment of FIG. **3**, opening **58** is axially offset from the radial center C of the valve body **52**. In other embodiments, valve **50** may have an opening disposed at the radial center of the valve body. Opening **58** is depicted in FIG. **3** as a generally circular aperture, however other structures and configurations are also contemplated. For example, opening may comprise one or more slits.

Disk valve **50** has a nipple **60** that extends outwardly and away from the first surface **54** of the valve body **52**. Nipple **60** has a base B attached to the valve body **52** and extends outwardly towards head H (see FIG. **7**A). Nipple **60** and opening **58** are each axially offset from the radial center C of the valve body **52** and are axially offset from each other. The distance between nipple **60** and opening **58** may vary by design. Thus, in some examples, nipple **60** and opening **58** may be axially aligned.

Nipple **60** is sized and configured to engage and seal an opening in a valve to limit communication through the valve (described further below). The shape, size, and configuration of the nipple can vary. To facilitate engagement of the nipple **60** with the opening, the head H preferably has a radial dimension that is less than, or equal to, the radial dimension of the opening to be sealed (see for example FIG. **4**, described below). To facilitate sealing, at least a portion of the nipple should preferably have a radial dimension that is equal to, or greater than, the radial dimension of the opening to be sealed. This "sealing" region is denoted in FIG. **7**A as "S."

In the embodiments of FIGS. **3**, **7**A, and **7**B, the nipple **60** is generally frustoconical and has a diameter that increases towards the base B. The cone or frustum may have a circular cross-section, as shown, or a non-circular cross-section (for example, a square contour). In some examples, a nipple may be provided with a "snap-fit" structure (not shown), such as one or more annular depressions, ridges, crests, or the like, that cooperate with a valve opening to form a reversible mechanical interlock between the nipple and opening. Such a structure may further enhance the integrity of the seal.

Nipple **60** may be attached to the valve body **52** by conventional means such as fusing, welding, adhering, or the like. In preferred examples, the nipple **60** and valve body **52** have a monolithic structure and may be formed, for example, by casting, molding, thermoforming, pressure forming, or like technique.

FIG. **4** depicts an exploded view of a valve device **70** with disk valves **52**A, **52**B. Valve **52**A comprises a valve body **53**A having a first surface **54**A, a second surface **56**A, and an opening **58**A between the first and second surfaces. Valve **52**B comprises a valve body **53**B having a first surface **54**B, second surface **56**B, and opening **58**A between the first and second surfaces. Openings **58**A, **58**B are each axially offset from the radial center C of the disks **52**A, **52**B. Each valve body **53**A, **53**B comprises a nipple **60**B, **60**A. The valves **52**A, **52**B are arranged so that nipple **60**A is axially aligned with opening **58**A and nipple **60**B is axially aligned with opening **58**B. In this arrangement, nipples **60**A, **60**B each define a plug that is capable of entering, and sealingly engaging, a respective opening **58**A, **58**B. The nipples **60**A, **60**B are each designed so that, in use, their length is at least equal to the spacing distance D (shown in FIG. **6**) between valves **52**A, **52**B. In preferred examples, each nipple has a length that is greater than the spacing distance D. In some examples, a nipple may be provided with a length of 0.1 mm or greater, 0.2 mm or greater, or 0.5 mm or greater.

FIG. **5** depicts an exploded view of a device **10**, similar to the introducer device depicted in FIGS. **1** and **2** that includes a valve **70**, similar to the valve depicted in FIG. **4**. In this example, two disk valves **52**A, **52**B are used instead of the four disk valves depicted in FIG. **2**. Valves **52**A, **52**B are arranged so that nipple **60**A (hidden) is axially aligned with opening **58**A and nipple **60**B is axially aligned with opening **58**B. Valves **52**A, **52**B are assembled within the valve housing **12** in relatively close proximity so that nipple **60**A can plug opening **58**A and nipple **60**B can plug opening **58**B. In use, fluid pressure within the haemostatic device **10** forces the valves **52**A, **52**B into intimate contact so that plug **60**A penetrates and covers the perimeter of opening **58**A and plug **60**B penetrates and covers the perimeter of opening **58**B.

FIG. **6** depicts a cross-sectional view of a portion of valve device **70** with nipple **60**A removably disposed within, and sealingly engaging, valve opening **58**A. This sealing structure results in a more robust seal between valves **52**A, **52**B than is possible with previously-known disk valves only, where fluid pockets may form due to decreased surface tension between the disks. As a result of this unique sealing structure, a two-body valve, like the one depicted in FIG. **4**, may have an improved pressure rating over a device using two, three, four, or more previously-known disk valves.

In the embodiments shown in FIGS. **4** and **5**, opening **58**A is axially offset from opening **58**B. These unaligned openings may present a challenge to the operator in navigating a medical device along multiple axes through the valve assembly. To facilitate this, the valve **70** system preferably has a structure that can guide a medical device between adjacent openings **58**A, **58**B. For example, nipple **60**A may have a dent **62** (shown in FIGS. **4**, **7**A, and **7**B) with a contour O that slopes outwardly and away from the center axis A of the nipple and towards opening **58**B (see also FIGS. **7** and **7**A). In the embodiment shown in FIGS. **7**A and **7**B, dent **62** has a tapered conical contour, although other contours may be provided or desired. Nipple **60**A and opening **58**A may cooperate to form a niche **64**, as shown in FIG. **8**. Niche **64** is formed by the adjacent radial surfaces of the dent **62**A and opening **58**A. In other embodiments, an opening may be provided with a dent (not shown), and a niche may be formed by adjacent radial surfaces of the dent and nipple.

Dent **62**A and niche **64** facilitate guiding a medical device, such as a guide wire, between openings **58**A, **58**B. In particular, the niche **64** structure is designed to locate and receive at least a portion of the medical device. Once the device is received in the niche **64**, the dent **62**A deflects it outwardly, and towards opening **58**B. This causes opening **58**A to stretch in a predetermined direction towards opening **58**B.

FIGS. **9**A-**9**D depict a haemostatic valve device **10** in stages of use. The device includes a valve housing **12** and two disk valves **52**A, **52**B disposed within the housing. Valve **52**A comprises a nipple **60**B that is removably disposed within, and sealingly engages, opening **58**B of valve **52**B. Likewise, valve **52**B comprises a nipple **60**A that is removably disposed within, and sealingly engages, opening **58**A of valve **52**A. Each of the nipples **60**A, **60**B has a dent **62**A, **62**B which, in cooperation with openings **58**A, **58**B, defines a niche **64**A, **64**B.

FIG. **9**A depicts the valves in a sealing configuration where nipple **60**A sealingly engages opening **58**A, and nipple **60**B sealingly engages opening **58**B, to limit fluid flow through the device. A guide wire **25** is shown disposed within the housing **12** and the tip of the guide wire is received within niche **64**A. When the guide wire **25** is pushed through opening **58**A, dent **62**A deflects and guides the tip of the guide wire toward and through opening **58**B.

In FIG. **9**B, the guide wire **25** is pushed through valve openings **58**A, **58**B, and displaces nipples **60**A, **60**B, thereby breaking the sealing engagement between nipples **60**A, **60**B and openings **58**A, **58**B. The wire **25** stretches opening **58**A radially in the direction of opening **58**B and opening **58**B radially in the direction of opening **58**A. The openings **58**A, **58**B deform about the wire **25** and create two opposing generally parabolic shapes that seal the curvature of the wire. The nipples **60**A, **60**B are displaced and, in some examples, may

slide behind the facing valve. FIGS. **9**C and **9**D depict views of the valve system with guide wire **12** passing through the valves **52**A, **52**B.

When the guide wire **25** is removed from the valve device, the openings **58**A, **58**B relax and contract towards their unexpanded configurations. As the openings contract, the nipples **60**A, **60**B sealingly engage a respective opening **58**A, **58**B, preventing fluid flow through the disks and, thereby, sealing the valve system. Due to their designed contour (shown, for example, in FIGS. **7**A and **7**B), the nipples **60**A, **60**B will fall in place naturally. Moreover, any pressure on either valve (such as fluid pressure on valve **58**B) will tend to force the nipples **60**A, **60**B into further engagement with the openings **58**A, **58**B, further improving the seal.

Throughout this specification various indications have been given as to preferred and different embodiments of the invention. However, it should be understood that the invention is not limited to any one of these. It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting. Moreover, the features of different embodiments may be combined together as no embodiment described above is intended to be an alternative of another.

It is to be understood that although the examples described above show the nipples being spaced from the apertures on the same disk, in some embodiments the nipples may be immediately adjacent these apertures. Such an arrangement provides a less tortuous path through the valve assembly for, for instance, a medical device.

The disclosures in U.S. patent application No. 61/221,343, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

The invention claimed is:

1. A haemostatic valve device comprising:

a first disk valve having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, a stretchable opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces, where the nipple is axially offset from the opening; and

a second disk valve having a valve body with a first surface facing in the first direction, a second surface facing in the second direction opposite the first direction, and a stretchable opening formed in the second valve body for providing communication through the second disk valve, where the first and second disk valves are arranged so that the nipple is removably disposed within, and sealingly engages, the opening of the second disk valve.

2. The device of claim **1** where the second disk valve further comprises a nipple, and where the second disk valve nipple is removably disposed within the opening of the first disk valve.

3. The device of claim **2** wherein the second disk valve nipple substantially sealingly engages the opening of the first disk valve.

4. The device of claim **1** where the first and second disk valves are separated by a spacing distance, and the nipple has a length that is equal to, or greater than, the spacing distance.

5. The device of claim **1** where the nipple and the first disk valve body comprise a monolithic structure.

6. The device of claim **1** where the nipple has a tapered contour.

7. A haemostatic valve device comprising:

a disk valve having a valve body with a first surface facing in a first direction, a second surface facing in a second direction opposite the first direction, a stretchable opening formed in the valve body for providing communication through the disk valve, and a nipple extending outwardly and away from at least one of the first and second surfaces, where the nipple is axially offset from the opening and comprises a dent having a contour that slopes towards the opening.

8. The device of claim **1** where the nipple is generally frusto-conical in shape.

9. The device of claim **1** where the nipple extends a distance of 0.1 mm or greater from the surface of the first disk valve and towards the opening of the second disk valve.

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